4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed extension of an existing collection of information pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and listing of ingredients in tobacco products.

DATES: Submit either electronic or written comments on the collection of information by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

(OMB Control Number 0910-0650)--Extension)

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301) by, among other things, adding a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(b) of the FD&C Act (21 U.S.C. 387e(b)), as amended by the Tobacco Control Act, requires that every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. Section 905(d) states that persons required to register under section 905(b) or 905(c) of the FD&C Act shall register any additional establishment that they own or operate in any state which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h) of the FD&C Act addresses foreign establishment registration

requirements, which will go into effect when regulations are promulgated by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants shall, at the time of registration under any such subsection, file with FDA a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the FD&C Act (21 U.S.C. 387d(a)(1)), as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and sub-brand. Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) of the FD&C Act must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" and (2) "Listing of Ingredients in Tobacco Products" to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed electronic submission applications to streamline the data entry process for registration and product listing and for ingredient listing. These tools allow for

importation of large quantities of structured data, attachment of files (e.g., in PDFs and certain media files), and automatic acknowledgement of FDA's receipt of submissions.

FDA also developed paper forms (Form FDA 3741--Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments, and Form FDA 3742--Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the electronic submission application and the paper forms can be accessed at http://www.fda.gov/tobacco. FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
Form FDA 3741: Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper Submission)/Section 905(b), 905(c), 905(d) 905(h), or 905(i) of the FD&C Act	125	1.6	200	3.75	750	$0.98
Form FDA 3742: Listing of Ingredients (Electronic and Paper Submissions)/Section 904(a)(1) or 904(c) of the FD&C Act	125	1.6	200	3	600	$0.98
Obtaining a DUNS Number (10% of Total Respondents)	8	1	8	.5 (30 minutes)	4	
Total					1,354	$1.96

Since this collection of information was last approved by OMB on October 15, 2012, its burden has remained the same at 1,354 reporting hours. This burden estimate was determined as a result of FDA experience over the past 3 years in the regulation of tobacco products and is based on the actual number of establishment registration and product listings and product ingredient submissions received during this time period. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will remain at 3.75 hours per establishment and, based on the actual number of registration information submitted in the past 3 years and its experience, the Agency estimates that approximately 200 registrations will be

submitted from 125 tobacco product establishments annually, for a total of 750 reporting burden hours. FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will remain at 3 hours per tobacco product and, based on the actual number of product ingredient listings submitted over the past 3 years and its experience, the Agency estimates that approximately 200 ingredient listings will be submitted from 125 tobacco establishments, for a total of 600 reporting burden hours.

FDA also estimates that obtaining a Dun and Bradstreet (DUNS) number will take 0.5 hours, and that 8 respondents (1 percent (1.25) of establishments required to register under section 905 and 5 percent (6.25) of submitters required to list ingredients under section 904) will not already have a DUNS number. The total burden is estimated to be 4 hours. Total burden hours for this collection, therefore is 1,354 hours.

Dated: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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